

REMARKS

The above referenced application has been reviewed in light of the Final Office Action mailed November 17, 2009. Claims 1-23 are currently pending in this application with claims 1, 15, and 21-23 being in independent form. Entry of the present response and favorable reconsideration of the present application are respectfully requested in view of the following remarks.

Claims 1-13, 15-19, and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,792,074 to Turkel et al. (hereinafter, Turkel). Applicant respectfully submits that each of independent claims 1, 15, and 23 is allowable over Turkel because Turkel fails to disclose each and every element of the independent claims as required under 35 U.S.C. §102(b). Accordingly, the rejection of each of claims 1, 15, and 23 as being anticipated under 35 U.S.C. §102(b) over Turkel is respectfully traversed.

According to §2131 of the MPEP, to anticipate a claim, the reference must teach each and every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Independent claim 1 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a

pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the distal end portion of the instrument introducer as it is advanced therethrough.

An exemplary illustration of an embodiment of the present application is shown in Figures 3 and 3A, reproduced below. The distal end portion defines a pocket 30 having an annular wall with an axial length and includes a substantially planar distal end wall configured and adapted to stretch and conform to the shape of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument. As illustrated and described in the specification, the annular wall is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and the distal end wall remains in contact with an outer surface of the surgical instrument "S" as the surgical instrument is advanced therethrough and stretches the instrument introducer.

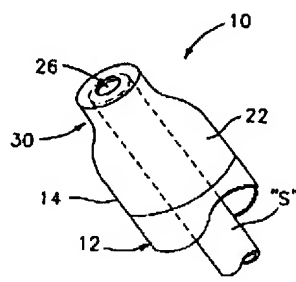


FIG. 3

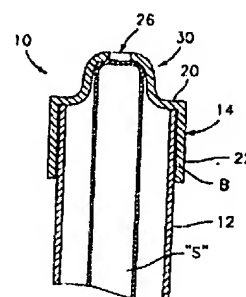
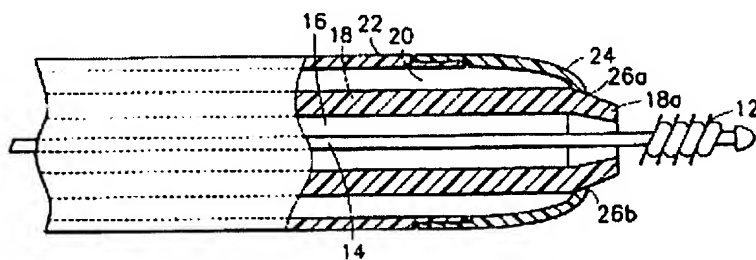
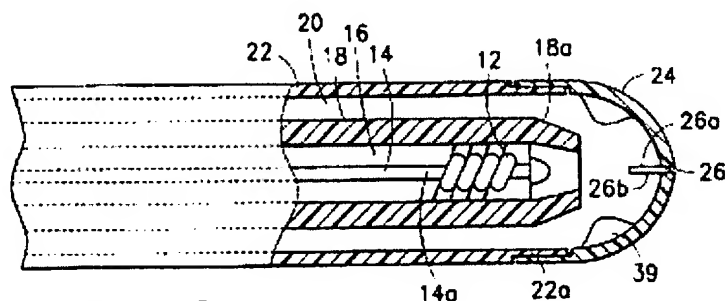


FIG. 3A

Turkel discloses, and illustrates in Figures 2a and 4 (reproduced below), a protected microbiological sampling brush assembly 10 including a sampling brush 12, an inner catheter 18 which houses the brush 12, an outer catheter 22 which houses the inner catheter 18, and an elastomeric tip 24 which is rigidly attached to the distal end 22a of the outer catheter 22. The elastomeric tip 24 is "substantially hemispherical" (see, claim 1) and has a weakened end in the form of a distal slit 26. The distal slit 26 defines lips 26a and 26b which are parted by contact with distal end 18a of catheter 18 and thus, only the edge of lips 26a and 26b of tip 24 are in contact with the outer surface of catheter 18.



Applicant respectfully submits that Turkel fails to anticipate each and every element of claim 1, in that Turkel fails to disclose a pocket having an annular wall with an axial length such that the annular wall is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket. In contrast, Turkel only discloses the distal end 18a

of catheter 18 contacting lips 26a and 26b of distal end 26 of outer catheter 22, and fails to disclose or illustrate the annular wall being in any contact with the surgical instrument along any portion of the length thereof. Moreover, Turkel also fails to disclose the pocket including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation to the surgical instrument. The distal end of Turkel is substantially hemispherical and Turkel only discloses parting of the lips upon movement of the inner catheter therethrough and sealing after withdrawal of the catheter from the elastomeric tip, not a pocket having an annular wall with an axial length that contacts the instrument and stretching of the distal end wall to conform to the shape of the inner catheter to facilitate passage in a sealing relation.

Accordingly, since Turkel does not disclose or suggest each and every element of claim 1, Applicant respectfully submits that the rejection of claim 1 as being anticipated under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 2-13 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-13 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

Independent claim 15 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a hollow elongate cylindrical body and an elastomeric cap secured to the distal end portion of the cylindrical body, the cap defining

a pocket having a annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall, the distal end wall including an aperture formed in the pocket configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument therethrough in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

Since claim 15 requires that the surgical instrument contacts the annular wall of the pocket and stretches the aperture and/or distal end wall of the pocket, similar to claim 1, for at least the reasons that claim 1 is allowable over Turkel, Applicant submits that claim 15 is also allowable over Turkel. Moreover, claim 15 also recites "the substantially planar distal end wall having an outer terminal edge and an annular side wall depending from the outer terminal edge." Turkel is devoid of this feature as the distal end is described and shown as being substantially hemispherical, thereby lacking a substantially planar distal end wall. Therefore, Applicant respectfully submits that the rejection of claim 15 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Turkel.

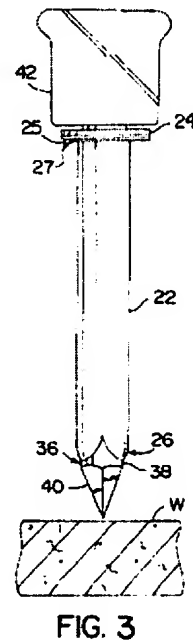
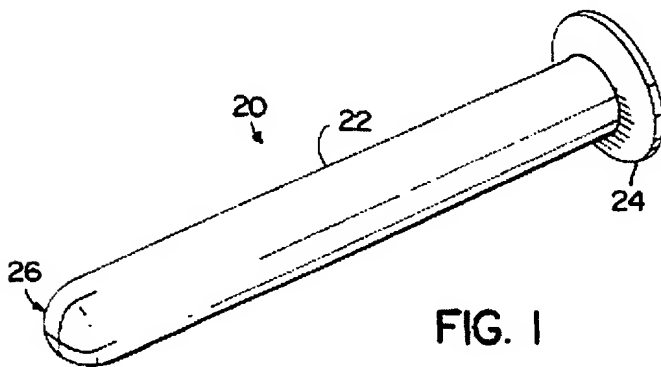
Independent claim 23 recites, in pertinent part, a surgical instrument and instrument introducer assembly comprising, *inter alia*, a surgical instrument for performing a surgical procedure and an instrument introducer assembly including a tubular body portion defining a lumen therethrough and a distal end portion secured to the distal end of the tubular body portion, the distal end portion defining a pocket including a substantially circular distal end wall and an annular wall depending from the circular distal end wall to the tubular body portion, wherein the annular wall is configured and adapted to contact an outer surface of the surgical instrument and facilitate passage of the surgical instrument therethrough, wherein the distal end wall of the distal end portion includes an aperture formed therein configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument in a sealing relation to the surgical instrument, wherein the surgical instrument stretches the aperture of the distal end wall of the instrument introducer as it is advanced therethrough.

Since claim 23 requires that the surgical instrument contacts the annular wall of the pocket and stretches the aperture and/or distal end wall of the pocket, similar to claim 1, for at least the reasons that claim 1 is allowable over Turkel, Applicant submits that claim 23 is also allowable over Turkel. Therefore, Applicant respectfully submits that the rejection of claim 23 under 35 U.S.C. §102(b) in view of Turkel should be withdrawn.

Claims 1-9, 11, 12, 15-19, and 21-23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,752,970 to Yoon (hereinafter, Yoon). Applicant respectfully submits that each of independent claims 1, 15, 21, 22, and 23 is allowable over Yoon because Yoon fails to disclose each and every element of the independent claims as required under 35

U.S.C. §102(b). Accordingly, the rejection of each of claims 1, 15, 21, 22, and 23 as being anticipated under 35 U.S.C. §102(b) over Yoon is respectfully traversed.

Yoon discloses a cannula for introducing medical instruments into an anatomical cavity. The cannula includes an elongate tubular body defining a lumen and a valve protruding distally from the tubular body for preventing fluid flow through the lumen when medical instruments are withdrawn from the anatomical cavity into the tubular body. In embodiments, as illustrated in Figures 1 and 3, the valve includes four valve members or flaps, each having a generally spherical triangular shape to sealingly mate with one another when closed and “to form a hemispherical or rounded wall closing the distal end of the tubular body.” (Col. 4, lines 5-6). Contrary to the Office Action, Figure 3 fails to illustrate a pocket with an annular wall being in contact with an outer surface of the surgical instrument along substantially the length of the pocket.



The Office Action pointed to the valve of Figure 15 as disclosing a substantially planar distal end wall. However, this valve is described at Col. 7, lines 37-40 as being similar to the valve described above (i.e., having a hemispherical or rounded wall closing the distal end, as shown in FIG. 1), but also having the additional feature of being detachable. Applicant asserts that Figure 15 does not disclose a substantially planar distal end wall or the pocket having an annular wall as required by the present claims.

Therefore, Applicant respectfully submits that Yoon fails to anticipate each and every element of claims 1, 15, 21, 22, and 23 as Yoon fails to disclose, *inter alia*, a pocket having an annular wall configured and adapted to contact an outer surface of the surgical instrument or the pocket including a substantially planar distal end wall. Accordingly, since Yoon does not disclose or suggest each and every element of claims 1, 15, 21, 22, and 23, Applicant respectfully submits that the rejection of claims 1, 15, 21, 22, and 23 as being anticipated under 35 U.S.C. §102(b) in view of Yoon should be withdrawn.

Since claims 2-9, 11, and 12 depend, directly or indirectly, from claim 1 and contain all of the limitations of claim 1, Applicant respectfully submits that claims 2-9, 11, and 12 are also not anticipated under 35 U.S.C. §102(b) over Yoon. Furthermore, since claims 16-19 depend, directly or indirectly, from claim 15 and contain all of the limitations of claim 15, Applicant respectfully submits that claims 16-19 are also not anticipated under 35 U.S.C. §102(b) over Yoon. Accordingly, in view of the foregoing, Applicant submits that claims 2-9, 11, 12, and 16-19 are allowable under 35 U.S.C. §102(b) over Yoon.

Claim 10 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent No. 5,634,937 to Mollenauer et al. (hereinafter, Mollenauer). Applicant respectfully submits that Yoon and Mollenauer, either alone or in combination, fail to teach or suggest the claimed apparatus

As stated above, Yoon fails to disclose, among other things, a distal end portion defining a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough, as called for in claim 1.

Mollenauer fails to cure the deficiencies of Yoon. Mollenauer is relied upon for the recitation of a polypropylene introducer body. Because Mollenauer fails to disclose or suggest a surgical instrument and instrument introducer assembly as recited in independent claim 1, no combination of the references can render claim 1 obvious.

Additionally, as claim 10 depends from claim 1, and contains all the features of claim 1, Applicant respectfully submits that the subject matter of claim 10 as a whole is patentable over Yoon in view of Mollenauer for at least the reasons presented above regarding the patentability of claim 1. Accordingly, in view of the foregoing, since Mollenauer fails to cure the deficiencies of Yoon, Applicant submits that the subject matter of claim 10 as a whole is allowable under 35 U.S.C. §103(a) over Yoon and Mollenauer.

Claims 14 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Yoon in view of U.S. Patent Appl. No. 2002/0099258 to Staskin et al. (hereinafter, Staskin). Applicant respectfully submits that Yoon and Staskin, either alone or in combination, fail to teach or suggest the claimed apparatus.

As stated above, Yoon fails to disclose, among other things, a pocket having an annular wall with an axial length such that the annular wall of the pocket is substantially in contact with an outer surface of the surgical instrument along substantially the length of the pocket and including a substantially planar distal end wall configured and adapted to stretch and conform to a shape of the outer surface of the surgical instrument to facilitate passage of the surgical instrument in a sealing relation, wherein the surgical instrument stretches the instrument introducer as it is advanced therethrough, as called for in claims 1 and 15.

Staskin fails to cure the deficiencies of Yoon. Staskin is relied upon for the recitation of a distal end portion having a frustoconical profile including a concave annular side wall. Because Staskin fails to disclose or suggest a surgical instrument and introducer assembly as recited in independent claims 1 and 15, no combination of the references can render claims 1 and 15 obvious.

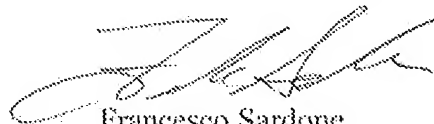
Furthermore, Staskin discloses a sling delivery system with a dilator. The dilator is attached to a needle through a shoulder on the dilator and corresponding recess in the needle. The dilator and needle are attached and not separated thereafter. (See Para. [0158] of Staskin).

As claim 14 depends from claim 1, and contains all the features of claim 1, Applicant respectfully submits that the subject matter of claim 14 as a whole is patentable over Yoon in view of Staskin for at least the reasons presented above regarding the patentability of claim 1. Furthermore, claim 20 depends from claim 15, and contains all the features of claim 15. Applicant submits that the subject matter of claim 20 as a whole is patentable over Yoon in view of Staskin for the reasons presented above regarding the patentability of claim 15. Accordingly, since Staskin fails to cure the deficiencies of Yoon, Applicant submits that the subject matter of claims 14 and 20 as a whole is allowable under 35 U.S.C. §103(a) over Yoon and Staskin.

In view of the foregoing amendments and remarks, Applicant submits that all of the claims are in proper format and are patentably distinct from the prior art of record and are in condition for allowance. The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Early and favorable response on the merits is earnestly solicited.

Respectfully submitted,



Francesco Sardone
Reg. No. 47,918
Attorney for Applicant(s)

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road - Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526